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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,326	10/06/2004	Jean-Marc Lefebvre-Despeaux	P25672	7542

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GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
06/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,326	LEFEBVRE-DESPEAUX ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-24,28,29,33,35 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12,13,17,18,23,24,29,35 and 36* is/are allowed.

6)☒ Claim(s) *9-11,14-16,19-22,28 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. Relative to the kit claims that are not limited to the 20-40 mmoles of NaOH that are shown in the compositions of the specification (table 1 on page 16) to have the pH required by claim 35, examiner notes that the kits are fully capable of making compositions outside of the claimed composition and there fore are not limited to the limitations of claim 35. Thus the scope of these claims is not limited by the scope of claim 35, but only by the limits of the composition as found in the kit claims themselves. For examination purposes, kit claims with an NaOH amount outside of the above 20-40 mmoles are subject to art that is not capable of meeting the composition of claim.

3. Claims 14, 21 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 14, the second receptacle is not complete since there are two possibilities for the composition of the first receptacle but only one possibility for the second receptacle. In claims 21 and 28, "the pill" does not have proper antecedent basis.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by McGrath (newly cited and applied). In the paper McGrath teaches forensic and clinical applications of a chemical luminescence test for blood. Forensic and clinical applications of the Specht test for the identification of suspected stains are considered. If a mist of a solution of 3-aminophthalic acid-hydrazide-HCl falls on a stain containing hematin, a marked bluish white luminescence appears which is clearly visible in the dark and can readily be photographed. The paper teaches 2 solutions that may be used: (a) 3-aminophthalic acid-hydrazide-HCl 1 gram (4.7 mmol/l) and Na_2O_2 5 grams (equivalent to H_2O_2 64 mmol/l and NaOH 128 mmol/l after reaction with water) in distilled water 1000 ml., or (b) 3-aminophthalic acid-hydrazide-HCl 1 g., Na_2CO_3 50 g., H_2O_2 (10 volume) 50, distilled water 1000 ml. The first solution is clearly anticipatory of a composition that is capable of being produced by the kit composition of claims 9-10. Very fresh

blood stains containing little hematin show little luminescence; the older the stain the greater the proportion of hematin present and the more marked the light effect. The reaction is specific. There is no reaction with serum, bile, sputum, pus, seminal stains, pleural fluid, feces, earth, fresh or rotting vegetable material, various paints, oils, metals, wood, wax, shoe polish or various other substances. It is not suggested, however, that at present the test be used as a final specific test for blood. The reaction can also be carried out in a test tube or on a slide. If a solution or suspension contains fresh blood, a few drops of NaOH solution (about 30%) are first added to form hematin. Warming increases the brilliance of the luminescence but shortens the duration. A clear positive reaction with blood can be obtained in dilutions over one in a million.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 9-11, 15-16, 19-22, 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGrath as explained above with regard to claims 9-10 or Takayama in view of Spiekermann (DE 19633808), Weber, Witz (US 3,959,081)and Byrne (US 5,770,116). McGrath teaches blood being detected, but does not specifically teach kits and the various possibilities for combining the components in a kit.

From the partial translation of the Takayama paper we have the following teaching. "(1) Put 100 mL of the 0.1N solution of the sodium hydroxide into the conical flask. Add and dissolve approximately 0.1 g of the Luminol (it is not necessary to completely dissolve the Luminol) (2) Add 10 mL of the 3% solution of hydrogen peroxide and mixed it gently." This

creates a reagent having a concentration of luminol is 5.1 mM/L, the concentration of sodium hydroxide is 90 mM/L, and the concentration of hydrogen peroxide is 80 mM/L. This is clearly anticipatory of a composition that is capable of being made by the claimed components in the kit of claims 9-10. Takayama teaches blood being detected, but does not specifically teach kits and the various possibilities for combining the components in a kit.

In the published application Spiekermann teaches an enhanced sanitation control of medical and dental tools by the chemical luminescent indicator luminol. The invention concerns the enhanced sanitation control of medical and dental tools by checking for blood residues after sterilization and disinfection using the chemical luminescent indicator luminol. The reagent is prepared from four components before the test and is either sprayed onto the tool or the tool is immersed into the reagent; the luminescent spots will indicate where to proceed with cleaning. Thus the components are aqueous sodium hydroxide, a 30% hydrogen peroxide solution, luminol in an alkaline aqueous solution, and water. Sensitivity of detection can be increased and documentation can be carried out by using a photographic film. The proposed invention can reveal directly or indirectly blood-contaminated instruments or equipment, particularly invisible residual blood contamination through simple application of the composition. Particular survival areas for microorganisms and function-impairing deposits can thus be simply visualized. Page 3, lines 60-66, at least, give information on the composition (see page 3 of the attached translation).

In the paper Weber teaches application of chemiluminescence of luminol in judicial medicine and toxicology. The blood concentration can be determined photoelectrically by the luminol reaction. Intensity-time curves are set up from which the maximum luminescence intensity and the total light can be obtained as a measurement of the blood concentration. Blood in traces of dry blood and fresh blood can be detected up to a dilution of 1:107 with a modified reagent using NaOH. A luminol reagent containing Na_2CO_3 instead of NaOH gave a different intensity-time curve with dry blood than with fresh blood. CO-containing dry blood traces just as fresh blood display only low luminescence intensity.

In the patent Witz teaches rapid identification of bacteria using chemiluminescence. Microorganisms containing hemoprotein substances with Fe porphyrin prosthetic groups can be specifically identified and differentiated by the characteristic time curves of chemiluminescence emission produced in the presence of luminol and H_2O_2. Thus, 0.2 ml luminol reagent

containing luminol 0.33, EDTA 5.00, and NaOH 20.00 g/l. and 0.2 ml H_2O_2 reagent containing H_2O_2 0.5% and acetophenetidin 0.0002% (column 3, lines 15-33) were mixed by injection into a test tube containing 1 ml of a microbial suspension, and the light output was monitored by an RCA 1P 21 photomultiplier tube connected to a Tektronic type 541A oscilloscope. Column 3, lines 15-23 teach that the luminol reagent was typically prepared by dissolving 0.33 grams luminol, 5.00 grams EDTA (disodium ethylenediaminetetracetic acid) and 20.00 grams NaOH in one liter of double distilled water. The purpose of the NaOH in the formulation is to give the preferred alkalinity (pH 11) so as to provide the optimum quantum yield for the reaction. It has been observed that the light output drops off markedly with a pH below 10.5.

In the patent Byrne teaches a kit comprising (i) a chemiluminescent chemical capable of emitting visible light on contact with animal blood, (ii) a peroxy oxidizing agent contained in a disposable packet, (iii) an aqueous solvent which is free from components that would inhibit the functioning of component (i), (iv) a vessel suitable for mixing components (i), (ii) and (iii), and (v) a device for delivering the resulting mixture as a spray to an area of terrain suspected of having blood deposits thereon, whereby said spray upon contact with said blood will luminesce and emit visible light enabling recognition by the hunter of the presence of said blood and to assist in tracking and located said wounded game animal. Use of a luminol compound is preferred. In a preferred embodiment, the kit contains a spraying device containing the appropriate amount of aqueous dissolving medium. Two containers or packets may be provided in the form of, for example, foil, plastic, or paper. One container or packet will contain the sodium perborate in a dry powder form, or as, for example, a compressed tablets. The second container will contain a mixture of luminol and sodium carbonate in a dry powder form, or as, for example, a compressed tablet or tablets. The respective packets or tablets will contain a pre-measured or dosed amount of the ingredients for mixing in the pre-determined volume of aqueous solvent. Column 3, lines 6-16 teach a variety of oxidizing agents to be used.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce kits using the compositions of McGrath or Takayama in detecting blood as taught by Spiekermann, Weber and Byrne in the various compositional forms/kits as taught by Spiekermann, Weber and Byrne because of the similarity in the compounds being detected, similarity of the detection reagent composition(s) and the need to and advantages of using a

luminescent material such as luminol in all of the references. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the NaOH amounts used in the McGrath or Takayama references to produce a solution with a pH of about 11 as taught by Witz because of the ability to provide the optimum quantum yield in use as taught by Witz.

8. Claims 12-13,17-18, 23-24, 29 and 35-36 are allowed.

9. Claim14 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. As noted above the changes to the claims include kit claims that while being capable of making the composition of claim 35 are also capable of making composition that lie outside of the scope of claim 35 such as those in the McGrath or Takayama references that have been reapplied against the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571)272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arlen Soderquist/
Primary Examiner, Art Unit 1797